additional information regarding the device necessary for FDA to file the PMA or to complete its review and make a final decision. The PMA applicant may, also on their own initiative, submit additional information to FDA during the review process. These amendments contain information ranging from additional test results, re-analysis of the original data set to revised device labeling. Almost all PMAs received by the Agency have amendments submitted during the review process. FDA estimates that 6,012 burden hours are necessary to satisfy this requirement.

• *PMA Supplements in § 814.39(a)*

FDA believes that the amendments mandated by FDAMA for § 814.39(f), permitting the submission of the 30-day notices in lieu of regular PMA supplements, will result in an approximate 20 percent reduction in the total number of hours as compared to regular PMA supplements. As a result, FDA estimates that 40,200 hours of burden are needed to complete the requirements for regular PMA supplements.

• *Special PMA Supplements—Changes Being Affected in § 814.39(d)*

These types of supplements are intended to enhance the safety of the device or the safe use of the device. The number of PMA supplements received that fit this category averaged 68 per year based on the numbers received from FY 2005 through FY 2009. Because of the minimal data required to be included in this type of supplement, FDA estimates that the burden hours necessary to satisfy this requirement are 408 hours.

• *30–Day Notice in § 814.39(f)*

Under section 515(d) of the act, modifications to manufacturing procedures or methods of manufacture that affect the safety and effectiveness of a device subject to an approved PMA do not require submission of a PMA supplement under § 814.39(a) and are eligible to be the subject of a 30-day notice. A 30-day notice shall describe in detail the change, summarize the data or information supporting the change, and state that the change has been made in accordance with the requirements of part 820 (21 CFR part 820). The manufacturer may distribute the device 30 days after the date on which FDA receives the 30-day notice, unless FDA notifies the applicant within 30 days from receipt of the notice, that it is not adequate. FDA estimates the burden to satisfy this requirement is 8,080 hours.

• *Post-Approval Requirements in § 814.82(a)(9)*

Post-approval requirements concern approved PMAs that were not reclassified and require a periodic report. After approval, all PMAs require a submission of an annual report. On average, approximately half of the submitted PMAs (18), require associated post-approval studies, i.e., followup of patients used in clinical trials to support the PMA or additional preclinical information, that is labor-intensive to compile and complete; the remaining PMAs require minimal information. Based on experience and consultation with industry, FDA has estimated that preparation of reports and information required by this section requires 2,430 hours.

• *Reports in § 814.84(b)*

Post-approval requirements described in § 814.82(a)(7) require submission of an annual report for each approved PMA. FDA estimates that respondents will average about 10 hours in preparing their reports to meet this requirement. This estimate is based on FDA's experience and consultation with industry. Thus, FDA estimates that the periodic reporting burden required by this section will take 6,480 hours.

Statutory Reporting Burden Estimate (FDAMA)

The total statutory reporting burden under the requirements of sections 201, 202, 205, 208, and 209 of FDAMA is estimated to be 1,230 hours. This burden estimate was based on actual real and estimated FDA data tracked from FY 2005 through FY 2009, and an estimate was also derived to forecast future expectations with regard to this statutory data.

Recordkeeping in § 814.82(a)(5) and (a)(6)

The recordkeeping burden under this section requires the maintenance of records, used to trace patients and the organization and the indexing of records into identifiable files to ensure the device's continued safety and effectiveness. These records are required only of those manufacturers who have an approved PMA and who had original clinical research in support of that PMA. For a typical year's submissions, 70 percent of the PMAs are eventually approved with 90 percent of these having original clinical trial data. Therefore, approximately 25 PMAs a year would be subject to these requirements. Also, because the requirements apply to all active PMAs, all holders of an active PMA application must maintain these records.

PMAs have been required since 1976, and there are 698 active PMAs that could be subject to these requirements, based on actual FDA data. Each study has approximately 200 subjects, and at an average of 5 minutes per subject, there is a total burden per study of 1,000 minutes, or 17 hours. The aggregate burden for all 698 holders of approved original PMAs, therefore, is 11,866 hours.

The applicant determines which records should be maintained during product development to document and/or substantiate the device's safety and effectiveness. Records required by the current good manufacturing practices for medical devices regulation (part 820) may be relevant to a PMA review and may be submitted as part of an application. In individual instances, records may be required as conditions of approval to ensure the device's continuing safety and effectiveness.

Dated: June 2, 2010.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2010–13763 Filed 6–7–10; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket Nos. FDA–2009–E–0165 and FDA–2009–E–0169]

Determination of Regulatory Review Period for Purposes of Patent Extension; ABLAVAR

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) has determined the regulatory review period for ABLAVAR (previously the trade name of the product was VASOVIST) and is publishing this notice of that determination as required by law. FDA has made the determination because of the submission of applications to the Director of Patents and Trademarks, Department of Commerce, for the extension of a patent which claims the human drug product.

ADDRESSES: Submit electronic comments to *http://www.regulations.gov*. Submit written petitions along with three copies and written comments to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Beverly Friedman, Office of Regulatory Policy, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 6222, Silver Spring, MD 20993–0002, 301–796–3602.

SUPPLEMENTARY INFORMATION: The Drug Price Competition and Patent Term Restoration Act of 1984 (Public Law 98–417) and the Generic Animal Drug and Patent Term Restoration Act (Public Law 100–670) generally provide that a patent may be extended for a period of up to 5 years so long as the patented item (human drug product, animal drug product, medical device, food additive, or color additive) was subject to regulatory review by FDA before the item was marketed. Under these acts, a product's regulatory review period forms the basis for determining the amount of extension an applicant may receive.

A regulatory review period consists of two periods of time: A testing phase and an approval phase. For human drug products, the testing phase begins when the exemption to permit the clinical investigations of the drug becomes effective and runs until the approval phase begins. The approval phase starts with the initial submission of an application to market the human drug product and continues until FDA grants permission to market the drug product. Although only a portion of a regulatory review period may count toward the actual amount of extension that the Director of Patents and Trademarks may award (for example, half the testing phase must be subtracted as well as any time that may have occurred before the patent was issued), FDA's determination of the length of a regulatory review period for a human drug product will include all of the testing phase and approval phase as specified in 35 U.S.C. 156(g)(1)(B).

FDA recently approved for marketing the human drug product ABLAVAR (gadofosveset trisodium). ABLAVAR is indicated for use as a contrast agent in magnetic resonance angiography to evaluate aortoiliac occlusive disease in adults with known or suspected peripheral vascular disease. Subsequent to this approval, the Patent and Trademark Office received patent term restoration applications for ABLAVAR (U.S. Patent Nos. 6,676,929 and 7,060,250) from Epix Pharmaceuticals, Inc., and the Patent and Trademark Office requested FDA's assistance in determining the patents' eligibility for patent term restoration. In a letter dated September 29, 2009, FDA advised the Patent and Trademark Office that this human drug product had undergone a regulatory review period and that the approval of ABLAVAR represented the first permitted commercial marketing or use of the product. Thereafter, the Patent and Trademark Office requested that FDA determine the product's regulatory review period.

FDA has determined that the applicable regulatory review period for ABLAVAR is 4,508 days. Of this time, 2,673 days occurred during the testing phase of the regulatory review period, while 1,835 days occurred during the approval phase. These periods of time were derived from the following dates:

1. *The date an exemption under section 505(i) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 355(i)) became effective*: August 21, 1996. FDA has verified the applicant's claim that the date the investigational new drug application became effective was on August 21, 1996.

2. *The date the application was initially submitted with respect to the human drug product under section 505(b) of the act*: December 15, 2003. FDA has verified the applicant's claim that the new drug application (NDA) 21–711 was submitted on December 15, 2003.

3. *The date the application was approved*: December 22, 2008. FDA has verified the applicant's claim that NDA 21–711 was approved on December 22, 2008.

This determination of the regulatory review period establishes the maximum potential length of a patent extension. However, the U.S. Patent and Trademark Office applies several statutory limitations in its calculations of the actual period for patent extension. In its applications for patent extension, this applicant seeks 1,806 days of patent term extension for U.S. Patent No. 6,676,929 and 924 days of patent term extension for U.S. Patent No. 7,060,250.

Anyone with knowledge that any of the dates as published are incorrect may submit to the Division of Dockets Management (see **ADDRESSES**) either electronic or written comments and ask for a redetermination by August 9, 2010. Furthermore, any interested person may petition FDA for a determination regarding whether the applicant for extension acted with due diligence during the regulatory review period by December 6, 2010. To meet its burden, the petition must contain sufficient facts to merit an FDA investigation. (See H. Rept. 857, part 1, 98th Cong., 2d sess., pp. 41–42, 1984.) Petitions should be in the format specified in 21 CFR 10.30.

Comments and petitions should be submitted to the Division of Dockets Management. Three copies of any mailed information are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document.

Comments and petitions may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Dated: April 23, 2010.

Jane A. Axelrad,

Associate Director for Policy, Center for Drug Evaluation and Research.

[FR Doc. 2010–13655 Filed 6–7–10; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration on Aging

Funding Opportunity: Affordable Care Act Medicare Beneficiary Outreach and Assistance Program Funding for Title VI Native American Programs

Purpose of Notice: Availability of funding opportunity announcement.

Funding Opportunity Title/Program Name: Affordable Care Act Medicare Beneficiary Outreach and Assistance Program Funding for Title VI Native American Programs.

Announcement Type: Initial.

Funding Opportunity Number: HHS–2010–AoA–MI–1022.

Statutory Authority: The Medicare Improvements for Patients and Providers Act of 2008—Section 119, Public Law 110–275 as amended by the Patient Protection and Affordable Care Act of 2010 (Affordable Care Act).

Catalog of Federal Domestic Assistance (CFDA) Number: 93.071. Discretionary Projects

DATES: The deadline date for the submission of applications is July 30, 2010.

I. Funding Opportunity Description

AoA will provide a grant of $1,000 to each Older Americans Act Title VI Native American program awardee. The purpose of these grants will be for the coordination of at least one community announcement and at least one outreach event to inform and assist eligible Native American elders about the benefits available to them through Medicare Part D, the Low Income Subsidy, the Medicare Savings Program, or Medicare prevention benefits and screenings. The example of $1,000 per event is for illustrative purposes only. There is data available from the National Association of Area Agencies on Aging (n4a) and studies performed by the National Council on Aging (NCOA) that reflect these costs for planning and implementing a community event for Medicare Part D and LIS outreach activities.

A detailed description of the funding opportunity may be found at *http://*